



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1162 and 1166

[Docket Nos. FDA-2021-N-1349 and FDA-2021-N-1309]

RIN 0910-AI60 and 0910-AI28

Establishment of Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars; Extension of Comment Period

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rules; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for two proposed rules that appeared in the *Federal Register* of May 4, 2022, which are a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes (“Tobacco Product Standard for Menthol in Cigarettes”; Docket No. FDA-2021-N-1349) and a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars (“Tobacco Product Standard for Characterizing Flavors in Cigars”; Docket No. FDA-2021-N-1309). The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rules published in the *Federal Register* on May 4, 2022 (87 FR 26454 and 87 FR 26396). Submit either electronic or written comments by August 2, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 2, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1349 for "Tobacco Product Standard for Menthol in Cigarettes" and/or Docket No. FDA-2021-N-1309 for "Tobacco Product Standard for Characterizing Flavors in Cigars." Received comments,

those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Nate Mease, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 4, 2022 (87 FR 26454 and 87 FR 26396), FDA published two proposed rules: (1) a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes (“Tobacco Product Standard for Menthol in Cigarettes”; Docket No. FDA-2021-N-1349) and (2) a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars (“Tobacco Product Standard for Characterizing Flavors in Cigars”; Docket No. FDA-2021-N-1309). Both proposed rules published with a 60-day comment period. Comments on the proposed rules will inform FDA’s rulemakings to establish tobacco product standards for menthol in cigarettes and characterizing flavors in cigars.

Interested persons were originally given until July 5, 2022, to comment on the proposed rules. We have received a number of requests for a 60-day extension of the comment period for both proposed rules, which conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful response to the proposed rules. Several organizations have requested that FDA close the comment period after 60 days, conveying that 60 days is enough time to receive meaningful responses and stressed a public health urgency with both product standards.

FDA has considered the requests and is extending the comment period for the proposed rules by an additional 30 days, until August 2, 2022. We believe that a 90-day comment period is appropriate as it allows adequate time for interested persons to fully consider the proposed rules, including specific requests for comments, and develop and submit comments without significantly lengthening the rulemaking proceedings.

Dated: June 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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